DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 18, 2014

ERBE USA, Inc.
John Tartal
Director of Quality and Regulatory Affairs
2225 Northwest Parkway
Marietta, GA 30067

Re: K143186
Trade/Device Name: ERBEFLO® 2 Endo QuickConnect Scope Port Connectors
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: OCX
Dated: December 3, 2014
Received: December 5, 2014

Dear John Tartal,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K143186

Device Name: ERBEFLO® 2 Endo QuickConnect Scope Port Connectors

Indications For Use:

The ERBEFLO® 2 Disposable Tubing System is intended to provide sterile water from a water source through an irrigation pump and an endoscope (or to an endoscope) for endoscopic procedures.

Prescription Use ___**X**___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ERBE USA Incorporated
Special 510(k) for ERBEFLO® 2 Endo QuickConnect Scope Port Connectors

510(k) SUMMARY

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	John Tartal Director of Quality and Regulatory Affairs
Date Prepared:	October 31, 2014
Trade/Proprietary Name:	ERBEFLO® 2 QuickConnect Scope Port Connectors
Common Name:	Endoscopic Irrigation Tubing System Accessory/Scope Port Connector
Classification Name and Code:	Endoscopes and Accessories (21 CFR Part 876.1500)
Product Code:	OCX
Legally Marketed Predicate Device:	ERBEFLO® 2 Disposable Tubing System, 510(k) Number K103235

Device Description:
The Endo QuickConnect Scope Port Connectors will be manufactured with medical grade materials or agents used in the medical device industry such as plastics, solvent, etc. The devices respectively adjoin an irrigation line of an ERBEFLO tubing/cap set to a designated gastrointestinal video endoscope. This line is a conduit for water to irrigate in endoscopic procedures. Each Port Connector has a standard female luer lock connection that attaches to an ERBEFLO tubing/cap set, backflow valve, and a scope specific connector (for an Olympus® or Pentax® Scope). The Port Connectors are provided sterile and are disposable.

Intended Use:
The ERBEFLO 2 Disposable Tubing System is intended to provide sterile water from a water source through an irrigation pump and an endoscope (or to an endoscope) for endoscopic procedures.

Note: The Endo QuickConnect Scope Port Connectors are additional accessories/single use connectors for the ERBEFLO® 2 Disposable Tubing System.

Similarities and Differences of the Proposed Device to the Current Device (Predicate Comparison/Substantial Equivalence):

Similarities

The Endo QuickConnect Scope Port Connectors will be a part of the ERBEFLO 2 Disposable Tubing System (i.e., they have the same intended use). The proposed Connectors have the same female connection and backflow valve as the predicate Connectors. Also, the same solvent for bonding is used for the proposed and predicate devices. The proposed and the predicate will be packaged in the same pouch, box, and carton and labeled in the same manner. Finally, the proposed and predicate devices are sterilized via Ethylene Oxide and are disposable.

Differences

The Endo QuickConnect Scope Port Connectors as compared to our current standard Connector's (predicate devices) hub is a softer/more pliable plastic with no o-ring or metal. The material for the hub of the Endo QuickConnect Scope Port Connectors is the same material used for hubs of other ERBEFLO products and has shown to be biocompatible and very durable. The proposed Connectors are slightly lighter and wider but shorter as compared to the predicate Connectors. No issues were found with the slight profile difference with either Connector. Finally, the scope connection of the proposed and predicate devices is slightly different. The proposed Olympus QuickConnector attaches to the Olympus Scope by pushing onto the port of the Scope as compared to our current Connector being screwed on. For the Pentax QuickConnector it is also pushed on like the current Connector but requires the removal of the Scope's port gasket. To ensure proper connection, these attachment differences are clearly defined in the Notes On Use and associated QuickStart Guides. Upon following proper connecting instructions, there were no flow issues (including no leaks). None of these differences impacted the safety or efficacy of the Endo QuickConnect Scope Port Connectors.

Evaluations and Testing:

The following evaluations and tests were performed on the Endo QuickConnect Scope Port Connectors to demonstrate safety and efficacy.

Biological Evaluation

The evaluation was performed per the current recognized standard and demonstrated that there were no biocompatibility issues with the materials used for the proposed products.

Performance Feasibility Testing

The feasibility testing showed that the flow performance of the proposed products was comparable to the predicate devices with no leaks. Additionally, the Endo QuickConnect Scope Port Connectors withstood the same backflow pressure as the current Connectors.

2X Sterilization Functional Testing

The testing demonstrated that the proposed products upon 2X sterilization met established performance specifications.

Packaging Evaluation
The evaluation demonstrated the adequacy and integrity of the packaging for the proposed products.
Sterilization Evaluation
The evaluation was performed using current recognized standards and demonstrated product sterility as well as meeting acceptable ethylene oxide residual levels prior to distribution.

Conclusion:
The intended use is the same for the Endo QuickConnect Scope Port Connectors as the current Connectors. The proposed devices have the same principles of operation and technological characteristics as the predicate devices. As compared to the predicates, the proposed Connectors are constructed with the same type of materials as well as have the same performance characteristics. In conclusion, the ERBEFLO 2 Endo QuickConnect Scope Port Connectors did not adversely affect safety or effectiveness.